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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/900,535	07/06/2001	Gary J. Fisher	100UM-011A(1718-011A)	3905

7590 06/18/2003

BRADLEY N. RUBEN, PC
463 FIRST STREET
SUITE 5A
HOBOKEN, NJ 07030-1859

EXAMINER

KIM, VICKIE Y

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 06/18/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/900,535

Applicant(s)

FISHER ET AL.

Examiner

Vickie Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 1-7 and 11-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 8-10 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7. 6) ☐ Other: _____

DETAILED ACTION

Status of Application

1. The election in responding to the restriction/election requirement issued 09/24/2002 is acknowledged. However, the examiner found the improper grouping of the patentably distinct inventions during the prosecution. Thus, the supplemental restriction is necessary to correct the problem. The supplemental restriction requirement is issued as follows and the instant office action supercedes any previous office action issued.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-3, drawn to a method of preventing MMP induction in human skin comprising applying one or more substance that block UVB radiation in the range of about 215-315nm and block UVA radiation in the range of about 365-395nm.
 - II. Claims 8-10, drawn to a method of manufacturing a sunscreen where the improvement comprising determining a candidate compound re-radiates in the region of greater than about 360nm upto about 400nm upon exposure to sunlight.
 - III. Claims 4-7, drawn to a method of treating fibrotic skin condition in a human patient normally having a light skin color, comprising providing a source of UVA radiation emitting in the range of greater than about 360nm upto about 400nm; and illuminating the affected area with radiation.

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- IV. Claims 11-18, drawn to a method of treating fibrotic skin condition comprising providing a source of radiation emitting in a wavelength selected from UVB of 295-315, UVA>360-400nm, and a combination thereof; and illuminating the affected area with radiation.
2. Inventions II is directed to process of manufacturing the product whereas I & III-IV are related as process of using. The use as claimed cannot be practiced with a materially different product. Since the product is not allowable, restriction is proper between said method of making and method of using (MPEP § 806.05(i)).
3. Inventions I, III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).
4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as and the search required for each group is not same, wherein a reference which anticipates the invention of Group I would not render the invention of Group II or III obvious, absent ancillary art, restriction for examination purposes as indicated is proper. Even if there were unity of classification, the search of entire groups and/or genus in the non-patent literature(especially, non-patent literature) and database search (a significant part of a thorough examination) would be burdensome, it is undue burden for examiner for the accurate and proper examination, restriction for examination purposes as indicated is proper.
5. During a telephone conversation with Mr. Ruben a provisional election was made to prosecute the invention of group II, claims 8-10. The telephonic interview was

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performed to confirm the election based on the supplemental restriction requirement mentioned above. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-7 and 11-18 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Election acknowledged

Applicant's affirmation on the election with traverse of Group II, claims 8-10 is acknowledged. Applicant traversed the restriction requirement on the grounds that there would be no burden in searching the entire application. This argument is not persuasive, as not all groups encompassed by the application would be classified together. As mentioned in previous office action, each invention is found to be patentably distinct subject matter proven in numerous patent literatures. The prevention of MMP induction(group I) or the treatment of the fibrotic skin conditions(group III) is also achieved by materially different substances. For instance, applicants themselves support the examiner's said allegation by claiming a method for treating a fibrotic condition by using tow different sources such as a substance of UVB radiation emitting in the range of about 295 –315nm or a substance of UVA radiation emitting in the range of >360-400nm, see instant claims 7 and 11. It also been known in the field that materially different substances such as retinoid or inhibitors of AP-1 prevent MMP induction, see 5837224. Therefore, even if there were unity of classification, the search of the entire application in patent and non-patent literature (a significant part of the thorough examination) would be burdensome due to the reasons mentioned in

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previous office action(e.g. patentably distinct subject matter proven in numerous patent literature). Therefore the restriction requirement is maintained and made FINAL.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 8-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 8-10 are drawn to a method of manufacturing a sunscreen by determining whether a candidate sunscreen compound re-radiates in the region of greater than about 360nm upto about 400nm upon exposure to sunlight, or not. However, there is no description of the identifying characteristics for recognizing that a candidate compound activates the region. At page 10, lines 16-20, the description about the said candidate compound is merely suggested. However, the structural identifying characteristics of the candidate compound are not disclosed. There is no evidence that there is any *per se* structure/function relationship between the disclosed candidate compounds and any others that might be found using the claimed method. Therefore, the claimed invention is not supported by an adequate written description.

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3. Claims 8-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the improvement comprising a candidate compound is not re-radiating in the region >360nm-400nm, does not reasonably provide enablement for the improvement comprising a candidate compound re-radiates in the region >360nm-400nm. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. At page 10, lines 13-15, the instant specification teaches that a compound re-radiates in the region >360nm-400nm is harmful. Thus, the instant claims are not enabled.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 9 recites the limitation "the UVA range" in claim 8. However, UVA has not recited in claim 8. There is insufficient antecedent basis for this limitation in the claim.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

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1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 8-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 4 of U.S. Patent No. 6,365,630. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims included in US'630 teaches that an improved pharmaceutical composition comprising UVA blocker that prevents the penetration of UVA radiation having the wavelength >360nm-400nm. Thus, the claimed subject matter (i.e. improvement comprising determining blocking re-radiated UVA radiation of about >360nm-400nm) is encompassed by the teaching of the US'630 because improved sunscreen by preventing penetration of harmful UVA radiation to skin by blocking harmful UVA radiation(>360nm-400nm) that is generated from different sources such as re-radiation or irradiation should be commensurated in the scope of the patented invention. It is noted that the re-radiation of the sunscreen is already well acknowledged by the skilled artisan(i.e. the sunscreens re-radiate the energy from photons absorbed) as also evidenced by applicant's own admission(see, page 9, line 4). Thus, it would have been obvious to one of ordinary skilled artisan to block any harmful radiation penetration whether the radiation is originated from solar light or re-radiation. It would have been obvious to one of ordinary skill in the art at the time of the invention

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was made to make the composition by screening the harmful UVA radiation with wavelength of about >360nm-400nm not only from direct solar radiation but also from the re-radiation.

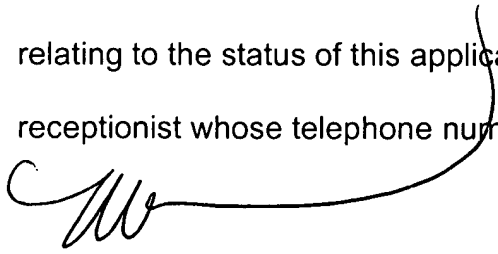
Thus, the claimed subject matter is not patentably distinct and considered to be unpatentable over U.S. Patent No. 6,365,630 and subject to double patenting rejection.

Conclusion

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 703-305-1675.

The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-3165 for regular communications and 703-746-3165 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Vickie Kim,
Patent examiner
June 15, 2003
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